**IN THE UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF IOWA**
**WESTERN DIVISION**

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| THE SECURITY NATIONAL BANK OF SIOUX CITY, IOWA as conservator for J.M.K., a Minor,<br><br>PLAINTIFF,<br><br>vs.<br><br>ABBOTT LABORATORIES,<br><br>DEFENDANT. | Case No. C11-4017-DEO<br><br>**COMPLAINT**<br>**JURY DEMAND** |

**COMES NOW** J.M.K., by and through her conservator The Security National Bank of Sioux City, Iowa ("Plaintiff"), and for her cause of action against Defendant Abbott Laboratories states and respectfully alleges as follows:

## I. PARTIES, JURISDICTION AND VENUE

1. J.M.K. is a resident of the City of Sioux City, County of Woodbury, State of Iowa.

2. The Security National Bank of Sioux City, Iowa has been appointed as the conservator for J.M.K. pursuant to a January 7, 2011 order from the Iowa District Court in and for Woodbury County, Probate No.GCPRO52050.

3. Defendant Abbott Laboratories is a corporation incorporated in the State of Illinois. Hereinafter, Defendant Abbott Laboratories shall be referred to as "Abbott."

4. At all times relevant, Abbott was engaged in the business of manufacturing, distributing, selling, and marketing its products, including Similac powdered infant formula (hereinafter "PIF"), to the public in the State of Iowa.

5. Abbott is an active registered foreign corporation with the State of Iowa. CT Corporation System, Inc. is the registered agent for this entity in the State of Iowa.

6. Abbott does not have a principal place of business in Iowa.

7. Subject matter jurisdiction in this matter is proper based on the diversity of the parties, and the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000), as required under 28 U.S.C. § 1332(a)(2).

8. Venue of this matter is proper in the United States District Court for the Northern District of Iowa, Western Division, pursuant to 28 U.S.C. § 1391(a), as a substantial part of the events or omissions giving rise to the claim set forth herein occurred in this judicial district.

## II. GENERAL FACT ALLEGATIONS

### J.M.K.'s INJURY

9. In April 2008, at St. Luke's Regional Medical Center of Sioux City, County of Woodbury, State of Iowa, J.M.K. was born.

10. J.M.K. was a full term healthy newborn.

11. J.M.K. was discharged from the St. Luke's Regional Medical Center of Sioux City approximately 3 days after her birth.

12. During her first 28 days of life, J.M.K. was a neonate (an infant younger than 28 days of age) and had a normal immune system for her age.

13. Upon discharge from St. Luke's Regional Medical Center of Sioux City on April 17, 2008, J.M.K.'s mother was given an unsolicited gift bag containing Similac PIF and liquid infant formula manufactured by Abbott.

14. The lot number, batch number, and expiration date for the Similac PIF contained in the gift bag were follows: expiration date: February 1, 2010, Batch Number: 281, Lot Number 61281RE1 011 0748.

15. The production date for the Similac PIF contained in the gift bag was January 2008. It was produced at Ross Product Division of Abbott Labs, Casa Grande, Arizona.

16. Similac PIF which Abbott produced at its Casa Grande plant in October 2007 and December 2007 tested positive for *Campylobacter*, a similar bacteria.

17. *Campylobacter* bacterium is a cause of food borne disease and/or illness in the United States.

18. Beginning on April 17, 2008, J.M.K.'s mother fed J.M.K. only the liquid infant formula until the supply contained in the gift bag was all consumed.

19. On April 24, 2008, J.M.K.'s mother began feeding J.M.K. the Similac PIF from the PIF contained in the Abbott gift bag received at discharge. J.M.K. was ten days old at this time.

20. J.M.K.'s mother boiled the water, utensils, bottles and all bottle parts she used with the PIF. J.M.K's mother prepared the PIF in her kitchen.

21. The Federal Drug Administration labs tested for and did not find E. sakazakii in J.M.K.'s kitchen.

22. On April 24, 2008, after being fed the Similac PIF, J.M.K. began showing signs of a possible infection and J.M.K.'s mother took her to the emergency department at St. Luke's Regional Medical Center of Sioux City where she was admitted.

23. On or about April 26, 2008, St. Luke's Regional Medical Center of Sioux City flew J.M.K. to the Children's Hospital and Medical Center in Omaha, Nebraska where J.M.K. was admitted and diagnosed with neonatal *Enterobacter sakazakii* meningitis.

24. The neonatal *Enterobacter sakazakii* meningitis resulted in severe brain damage to J.M.K.

25. Neither J.M.K.'s parents, J.M.K., nor the ordinary consumer would reasonably expect Abbott's food product to contain the *Enterobacter sakazakii* that caused the harm to J.M.K.

26. Abbott's product was used in the manner in which Abbott intended by J.M.K and her parents.

27. J.M.K's use and ingestion of the PIF was reasonably foreseeable, anticipated and normal.

28. Feeding PIF to infants, including neonates and premature infants, is an intended, reasonably foreseeable, anticipated and normal use of the product.

29. Abbott's products were not and are not reasonably safe for premature babies, babies with immune problems and/or neonates, whether or not the neonate is full term and whether or not the neonate is healthy and has a normal immune system for that age.

## CAUSE OF INJURY

30. The only known cause of neonatal *Enterobacter sakazakii* meningitis is food-borne ingestion of *Enterobacter sakazakii*.

31. PIF is the only known source of neonatal *Enterobacter sakazakii* meningitis.

32. Every case of neonatal *Enterobacter sakazakii* meningitis documented by the Centers for Disease Control has been associated with PIF except one. In that case, which

presents the sole exception, it is believed that the infant may have been fed its twin's PIF because of an admitted crib card switch resulting in misidentification.

33. Dr. Anne Bowen of the CDC stated in 2007 that for infants: "There has been no documented transmission of *Enterobacter sakazakii* other than through consumption of contaminated powdered formula."

34. The source of bacteria that caused J.M.K.'s neonatal *Enterobacter sakazakii* meningitis was Abbott's Similac PIF.

35. The *Enterobacter sakazakii* that caused J.M.K.'s neonatal *Enterobacter sakazakii* meningitis originated from the bacteria colony or its progeny that contaminated Abbott's PIF facilities, and/or Abbott's finished product PIF prior to distribution, and/or PIF consumed prior to the diagnosis of *Enterobacter sakazakii* infection.

36. Matching J.M.K.'s *Enterobacter sakazakii* DNA with an *Enterobacter sakazakii* isolate found in Abbott's factory, manufacturing equipment, raw materials, finished product (before or after distribution) or with one found in another baby following ingestion of Abbott's PIF will determine the source of the contamination.

37. After being alerted in 2001, the FDA tested samples of PIF taken at PIF manufacturing facilities and, as reported in March 2004, found that 23 percent contained *Enterobacter sakazakii.*

38. On information and belief, between March 29, 2002 and September 19, 2006, environmental sampling from Abbott's PIF facility and/or facilities tested positive for *Enterobacteriaceae (Eb)* which is the family containing *Enterobacter sakazakii* and/or *Enterobacter sakazakii.*

39. On information and belief, between March 29, 2002 and September 19, 2006, raw ingredient sampling from Abbott's PIF finished product tested positive for *Enterobacter sakazakii.*

40. On information and belief, between March 29, 2002 and September 19, 2006, finished product sampling from Abbott's PIF finished product prior to consumer distribution tested positive for *Enterobacter sakazakii.*

41. Abbott knew prior to October 2004 that its PIF is not sterile, that it is not reasonably safe and that it should not be fed to premature infants, neonates, or infants of any age who might have immune problems.

42. When *Enterobacter sakazakii* contaminates a can of PIF, the *Enterobacter sakazakii* is not uniformly distributed throughout the powder in the can, but rather, clumps in one or several places so that remaining powder is likely without the *Enterobacter sakazakii* consumed.

43. PIF, regardless of brand, can be potentially contaminated with *Enterobacter sakazakii* before distribution to the consumer because it is not manufactured as commercially sterile.

44. Although Abbott manufactures different versions of Similac PIF, all of the versions which it manufactures are basically the same, as the products share the same basic raw ingredients; manufacturing facilities, process and equipment; filling and packaging equipment, and finished product storage areas.

45. The sources of contamination in all versions of PIF are shared manufacturing facilities, manufacturing equipment and/or raw ingredients.

46. Manufacturing and/or design defects existed which caused *Enterobacter sakazakii* to be introduced into Abbott's PIF.

47. By providing a sample of its PIF, unsolicited, without any warning or, in the alternative, without an adequate warning concerning its use by neonates with normal immune systems for their age and/or by premature infants, Abbott distributed its product in willful and wanton disregard for the rights and/or safety of J.M.K.

48. Abbott had a duty to provide a reasonably adequate warning for its product to those who use the product as intended or in a way that Abbott could have reasonably foreseen.

49. Abbott failed to adequately warn parents of premature infants and neonates with normal immune systems for their age that Abbott's products are not reasonably safe.

**SAFE ALTERNATIVE**

50. Abbott manufactures and sells liquid infant formula which is sterile and does not contain *Enterobacter sakazakii*.

51. Liquid infant formula has no known association with neonatal *Enterobacter sakazakii* meningitis.

52. Because liquid infant formula is sterile, it is a safe alternative for neonates, premature infants and infants with immune problems.

53. Abbott's liquid infant formula was and is a reasonable alternative safer design that could have been practically adopted at the time of sale or distribution of the PIF to J.M.K.

54. The alternative design would have reduced or avoided the foreseeable risks of harm posed by the PIF.

## III. CAUSES OF ACTION

**COUNT 1-DEFECTS OF MANUFACTURING**

55. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 54 above.

56. On information and belief and in the alternative, either Abbott's PIF that J.M.K. consumed deviated in a material way from Abbott's specifications and/or performance standards and was, therefore, not reasonably safe to the ordinary consumer and/or neonate in composition (i.e. a manufacturing defect), or Abbott's specifications and/or performance standards were deficient and caused unsafe PIF to enter the market and be consumed by J.M.K (i.e. a design defect).

57. At the time the PIF that was fed to J.M.K. and that caused her neonatal *Enterobacter sakazakii* meningitis left Abbott's control, it contained a manufacturing defect that departed from its intended design, in one or more of the following ways:

a. Storage occurred in areas without proper climate control allowing condensation that permitted *Enterobacter sakazakii* to grow.

b. The finished PIF was not biocidally treated in its end use containers.

c. Manufacturing and storage facilities were not kept sufficiently clean.

d. Abbott's PIF finished product testing procedures and methods were inadequate to discover *Enterobacter sakazakii* because, among other things, it is premised on uniform distribution of *Enterobacter sakazakii.*

e. The process for manufacturing the PIF involved shared manufacturing facilities, manufacturing equipment and/or raw ingredients.

f. The PIF contained *Enterobacter sakazakii.*

g. Discovery will likely find additional manufacturing defects during the relevant time period.

58. The PIF Abbott manufactured, distributed and sold was delivered to J.M.K. without any change in its defective condition.

59. The manufacturing defect(s) were a cause of J.M.K.'s damages.

60. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it manufactured the defective PIF.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

**COUNT 2-DEFECTS OF DESIGN**

61. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 60 above.

62. At the time the PIF that was fed to J.M.K. and that caused her neonatal *Enterobacter sakazakii* meningitis left Abbott's control it contained a defective condition or was defectively designed, in one or more of the following ways:

a. Storage occurred in areas without proper climate control allowing condensation that permitted *Enterobacter sakazakii* to grow.

b. The finished PIF was not biocidally treated in its end use containers.

c. Manufacturing and storage facilities were not kept sufficiently clean.

d. Abbott's PIF finished product testing procedures and methods were inadequate to discover *Enterobacter sakazakii* because, among other things, it is premised on uniform distribution of *Enterobacter sakazakii.*

e. The process for manufacturing the PIF involved shared manufacturing facilities, manufacturing equipment and/or raw ingredients.

f. The PIF contained *Enterobacter sakazakii*.

g. Discovery will likely find additional design defects during the relevant time period.

63. Reasonable alternative safer designs could have been practically adopted as alternative manufacturing and storage processes and/or designs were available.

64. These alternative manufacturing and storage designs included biocidally treating finished PIF in its end-use containers, storing the product in proper climate-controlled areas, and maintaining the manufacturing and storage facilities in a sufficiently clean condition.

65. A reasonable alternative safer design that could have been practically adopted would have been to distribute only liquid infant formula to neonates such as J.M.K.

66. A reasonable alternative safer design that could have been practically adopted at the time of distribution would have been implementation of product testing procedures that adequately tested for *Enterobacter sakazakii*.

67. The alternative design(s) would have reduced or avoided the foreseeable risks of harm posed by the PIF by decreasing the incidence of *Enterobacter sakazakii* in Abbott's PIF at the time J.M.K's parents acquired the product to a level that would have prevented J.M.K.'s infection.

68. Abbott failed to implement, in a timely and immediate fashion, those manufacturing and storage processes, or testing procedures, and/or other alternative designs that would have decreased the incidence of *Enterobacter sakazakii* in Abbott's PIF at the time J.M.K's parents acquired the product.

69. The omission of the alternative design(s) rendered the PIF not reasonably safe.

70. The alternative design(s) would have reduced or prevented the harm to J.M.K.

71. The design defects were a cause of J.M.K.'s damage.

72. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it distributed the PIF that was defective in design.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

**COUNT 3 – FAILURE TO WARN**

73. Plaintiff re-alleges and incorporates herein as if restated in full the allegations of paragraphs 1 through 72 above.

74. The foreseeable risks of harm posed by the PIF could have been reduced or avoided by the provision of reasonable instructions or warnings, in one or more of the following ways:

a. Abbott could have placed labels on the cans of PIF informing consumers and the public that it is not suitable for use with neonates with normal immune systems for their age and/or by premature infants;

b. Abbott could have informed consumers and the public through its advertising and marketing that PIF is not sterile and is not a safe option for neonates with normal immune systems for their age and/or by premature infants;

c. Abbott could have informed consumers and the public that only its liquid formula is sterile and safe for use in neonates with normal immune systems for their age and/or by premature infants;

d. Abbott could have accompanied its PIF with adequate and proper warnings regarding all possible risks, dangers, and adverse side effects associated with the use of its PIF, including risk of bacterial infection.

75. Abbott's inadequate warning and/or lack of warning made its products not reasonably safe to all infants and, in particular to full term neonates with normal immune systems for their age, such as J.M.K.

76. The risks to be addressed by the warnings or instructions were not obvious to, or generally known by, foreseeable product users.

77. The omission of instructions or warnings was a cause of J.M.K.'s damages.

78. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it distributed the PIF with inadequate warnings.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

## COUNT 4 – BREACH OF EXPRESS WARRANTIES

79. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 78 above.

80. When Abbott distributed its product to J.M.K., it accompanied the product with a label that expressly warranted that its product was beneficial and safe for infants, including neonates.

81. Upon information and belief, from 2006 through the present day, Abbott has expressly stated that its infant formula is microbiologically safe on its website, www.abbott.com.

82. Abbott currently states that "infant formula is the only safe, nutritious, and recommended alternative" to breastfeeding on its website www.abbottmama.com. Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

83. On December 23, 2008, in response to allegations that its infant formula contained melamine or cyanuric acid, Abbott issued a press release that stated that its "infant formulas are completely safe and we stand behind them." Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

84. In 2009, Abbott advertised its Similac PIF with photographs of very young babies along with statements, including the following:

a. "While you protect her on the outside, we'll help protect her on the inside."

b. "You'll help her stand on her own 2 feet. We'll help her immune system run."

c. "You'll feed his imagination. We'll help feed his immune system."

Said advertisements were ran in well known magazines such as People. Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

85. Discovery will likely find additional express warranties made by Abbott during the relevant time period.

86. The PIF was fed to J.M.K. in reliance on the express warranties that it was beneficial and safe for her.

87. The PIF did not conform to the express warranties and/or representations as it was not safe or beneficial for J.M.K.

88. Abbott breached an express warranty that induced the parents of J.M.K. to feed her PIF. Namely, that Abbott's PIF is both safe and beneficial for neonates with normal immune systems for their age.

89. The breach of the express warranty was a cause of J.M.K.'s damage.

90. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it expressly warranted that the PIF was safe and beneficial to babies, without excluding neonates.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

## COUNT 5 – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

91. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 90 above.

92. When Abbott distributed its product to J.M.K., it provided an implied warranty that its product was beneficial and safe for infants, including neonates.

93. Abbott specifically advertised and stated that its PIF was safe and beneficial to babies such as J.M.K.

94. At the time of the distribution to J.M.K., Abbott had reason to know the particular purpose of the PIF.

95. Abbott had reason to know J.M.K. was relying on its skill or judgment to furnish the PIF.

96. Abbott currently claims on its website fact sheet that "[e]ach line of formula in the Similac line provides the balance of protein, minerals and other nutrients that help give your baby a strong start in life. Moms can count on Similac for trusted nutrition and the formula that's

right for their babies." Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

97. J.M.K. relied on Abbott's skill or judgment when the PIF was fed to J.M.K.

98. The PIF was not fit for the particular purpose.

99. The failure of the PIF to fit the particular purpose was a cause of J.M.K.'s damage.

100. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it failed to manufacture the PIF in a manner which rendered it fit for the particular purpose of providing safe nourishment to J.M.K.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

## COUNT 6– BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

101. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 100 above.

102. Abbott was a merchant at the time the PIF was distributed to J.M.K.

103. The PIF was not merchantable when distributed to J.M.K.

104. The PIF was not in fair average quality because it contained *Enterobacter sakazakii* when it was distributed to J.M.K.

105. The PIF did not conform to the promises or affirmations of fact made on the container or label in that it was not safe and beneficial to J.M.K.

106. The PIF was not fit for the ordinary purposes of which it was used.

107. The lack of merchantability was a cause of J.M.K.'s damage.

108. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it breached the implied warranty of merchantability.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

**COUNT 7– FRAUD**

109. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 108 above.

110. Upon information and belief, from 2006 through the present day, Abbott has expressly stated that its infant formula is microbiologically safe on its website, www.abbott.com.

111. Abbott currently states that "infant formula is the only safe, nutritious, and recommended alternative" to breastfeeding on its website www.abbottmama.com. Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

112. On December 23, 2008, in response to allegations that its infant formula contained melamine or cyanuric acid, Abbott issued a press release that stated that its "infant formulas are completely safe and we stand behind them." Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

113. In 2009, Abbott advertised its Similac PIF with photographs of very young babies along with statements, including the following:

a. "While you protect her on the outside, we'll help protect her on the inside."

b. "You'll help her stand on her own 2 feet. We'll help her immune system run."

c. "You'll feed his imagination. We'll help feed his immune system."

Said advertisements were ran in well known magazines such as People. Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

114. Abbott currently claims on its website fact sheet that "[e]ach line of formula in the Similac line provides the balance of protein, minerals and other nutrients that help give your baby a strong start in life. Moms can count on Similac for trusted nutrition and the formula that's right for their babies." Upon information and belief, Abbott made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.

115. Discovery will likely find additional statements made by Abbott, during the relevant time period, that are misleading and required disclosure that PIF is unsafe for neonates with normal immune systems in order to prevent them from being misleading.

116. J.M.K. consumed the PIF in justifiable reliance upon statements of fact made by Abbott to consumers of its product.

117. Abbott failed to disclose to such consumers matters known to it that it knew to be necessary to prevent the statements of fact made to consumers from being misleading.

118. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it failed to disclose that its PIF is not safe for neonates with normal immune systems.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

## COUNT 8 – NEGLIGENT MISREPRESENTATION

119. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 118 above.

120. Abbott made representations and supplied information that its PIF was safe for infants or babies without limitation for neonates with normal immune systems. In particular, see the representations and statements referenced herein in paragraphs 109-113.

121. Discovery will likely find additional misrepresentations made by Abbott during the relevant time period.

122. Abbott had a pecuniary interest in supplying information related to its PIF to its consumers, including J.M.K.

123. Abbott intended to supply the information for the guidance of or to influence its consumers, including J.M.K.

124. Abbott's consumers, including J.M.K., acted in justifiable reliance upon the information supplied by Abbott, namely that its' PIF was safe.

125. Abbott failed to exercise reasonable care or competence in obtaining or communicating that its' PIF was safe for all infants, including neonates with normal immune systems.

126. The negligently supplied information was a proximate cause of damage to J.M.K.

127. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it represented that its PIF was safe for neonates with normal immune systems.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted

## COUNT 9 – NEGLIGENCE

128. Plaintiff re-alleges and incorporates herein as if restated in full the allegations of paragraphs 1 through 127 above.

129. At all relevant times to this action, Abbott owed a duty to J.M.K. to exercise reasonable care to properly prepare, design, research, test, develop, manufacture, inspect, label, market, promote, distribute, advertise and sell their PIF, a food product.

130. Abbott's duty of reasonable care included the duty not to introduce PIF into the stream of commerce that would cause users to suffer from unreasonable, dangerous and untoward adverse side effects and injury.

131. Abbott owed a duty to J.M.K. to inspect and test its PIF for contamination and defects and to adequately warn of the same.

132. Abbott knew, or in the exercise of reasonable care should have known, that if its PIF was not properly prepared, designed, researched, tested, developed, manufactured, inspected, labeled, marketed, promoted, distributed, advertised and/or sold, and its products were likely to be not reasonably safe and would cause injury to those who used them.

133. Abbott was negligent in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, advertising, distribution, promotion and selling of its PIF, a food product, in that it:

a. Failed to use due care in the preparation and development of its PIF to prevent the aforementioned risk of injuries to individuals when the formulas were ingested;

b. Failed to use due care in the design of its PIF to prevent the aforementioned risk of injuries to individuals when the formulas were ingested;

c. Failed to conduct adequate pre-clinical testing and research to determine the safety of its PIF;

d. Failed to conduct adequate post-marketing surveillance to determine the safety of its PIF;

e. Failed to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance to J.M.K. or her parents, the consumer, the medical community, and the FDA;

f. Failed to accompany its PIF with adequate and proper warnings regarding all possible risks, dangers, and adverse side effects associated with the use of its PIF, including risk of bacterial infection;

g. Failed to use due care in the manufacture, testing, inspection and labeling of its PIF to prevent the aforementioned risk of injuries of individuals who used its PIF;

h. Failed to use due care in the promotion of its PIF to prevent the aforementioned risk of injuries to individual when the formulas were ingested;

i. Failed to use due care in the advertisements in connection with the sale and marketing of its PIF to prevent the aforementioned risk of injuries to individuals when the formulas were ingested;

j. Failed to use due care in the distribution of its PIF to prevent the aforementioned risk of injuries to individuals when the formulas were ingested;

k. Failed to provide adequate and accurate training and information to the marketing representatives who marketed its PIF;

l. Failed to provide adequate and accurate training and information to healthcare providers for the appropriate use of its PIF;

m. Failed to apprise of the safe sterile alternative, liquid infant formula; and

n. Was otherwise careless and negligent.

134. Despite the fact that Abbott knew or should have known that its PIF caused unreasonable and dangerous side effects which many users would be unable to remedy by any

means, it continued to promote and market the PIF to consumers, including J.M.K., when safer and more effective products were available.

135. Abbott was or should have been in possession of evidence demonstrating that its PIF caused serious side effects. Nevertheless, it continued to market its products by providing false and misleading information with regard to the safety and efficacy of PIF.

136. Abbott knew or should have known that consumers such as J.M.K. would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

137. Abbott's negligence and breach of duties is a direct cause of J.M.K's injuries and damages.

138. Abbott acted in willful and wanton disregard of J.M.K's rights or safety when it failed to exercise of reasonable care in preparing, designing, researching, testing, developing, manufacturing, inspecting, labeling, marketing, promoting, distributing, advertising and/or selling of its products.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

## COUNT 10– STRICT PRODUCT LIABILITY

139. Plaintiff re-alleges and incorporates herein as if restated in full, the allegations of paragraphs 1 through 138 above.

140. The PIF that Abbott manufactured, distributed, and sold was defective and not reasonably safe for its ordinary and expected use at the time it left Abbott's control due to bacterial contamination.

141. The PIF that Abbott manufactured, distributed, and sold was defective and did not perform reasonably safely in its normal intended use or in a reasonably foreseeable use of the product.

142. The PIF was not reasonably safe because the danger was greater than an ordinary consumer with knowledge of the product would expect.

143. The PIF products are not sterile, and Abbott knew or should have known of the risks of contamination.

144. The PIF was used in the manner expected and intended, and was consumed by J.M.K.

145. J.M.K. suffered injury and damages as a direct and proximate result of the defective and unsafe condition of the PIF that Abbott manufactured, distributed and sold.

146. Abbott is strictly liable for its actions taken in willful and wanton disregard for the rights or safety of J.M.K. and the injuries and damages directly caused by the PIF.

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages as allowed by Iowa law, together with interest and costs as permitted.

## COUNT 11- PUNITIVE/EXEMPLARY DAMAGES

147. Plaintiff re-alleges and incorporates herein as if restated in full the allegations of paragraphs 1 through 146 above.

148. Abbott acted in willful and wanton disregard for the rights or safety of J.M.K.

149. Abbott's conduct was directed specifically at J.M.K.

150. J.M.K. is entitled to recover punitive/exemplary damages on all claims asserted herein in accordance with Iowa Code Section 668A.1 (2010).

**WHEREFORE** Plaintiff requests damages in an amount that will reasonably compensate J.M.K. for her injures and damages, as well as punitive/exemplary damages on all claims as allowed by Iowa law, together with interest and costs as permitted.

## PRAYER FOR RELIEF

151. As a direct and proximate result of Abbott's liability as manufacturer, and due to characteristics of Abbott's PIF, and the ingestion of Abbott's PIF, J.M.K. has suffered considerable damages, and prays for judgment against Abbott for damages which specifically include the following:

a. Neonatal *Enterobacter sakazakii* meningitis and permanent brain damage that will never allow independent living;

b. Past and future physical pain, suffering, and disability;

c. Past and future emotional distress, including, but not limited to, the justifiable fear of future disease;

d. Mental anguish;

e. The increased risk of contracting additional disease;

f. The need for medical monitoring;

g. Past and future medical expenses;

h. Serious and permanent impairments, both physical and mental;

i. Loss of the enjoyment of life's pleasures;

j. Loss of earnings, loss of future earnings, and/or the loss of earning capacity;

k. Punitive/exemplary damages; and

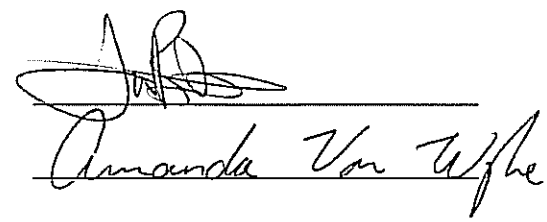
l. All such damages as are proven and found reasonable in the premises, including interest, costs and reasonable attorneys' fees as the Court finds just and equitable.

## JURY DEMAND

Plaintiff demands a trial by jury.

Dated this 15th day of February, 2011.

Respectfully Submitted By:



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